IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

MONIQUE D. ALMY, Chapter 7 Trustee For the Bankruptcy Estate of Bionicare Medical Technologies, Inc.,	*	
Plaintiff,	*	Civil Action No.: RDB-08-1245
v.	*	
KATHLEEN SEBELIUS, Secretary, United States Department of Health and Human Services	*	
Defendant.	*	

* * * * * * * * * * * * *

MEMORANDUM OPINION

Plaintiff Monique D. Almy ("Plaintiff"), the Chapter 7 trustee for the bankruptcy estate of Bionicare Medical Technologies, Inc.'s ("Bionicare" or "Supplier"), has filed this action against Kathleen Sebelius in her official capacity as Secretary of the United States Department of Health and Human Services (the "Secretary"). Plaintiff seeks judicial review and reversal of eight final decisions of the Secretary's Medicare Appeals Council concerning Medicare coverage and payment for claims relating to the BIO-1000, a medical device for treatment of osteoarthritis of the knee. Currently pending are the parties' cross-motions for summary judgment. The parties' submissions have been reviewed and a hearing was conducted on July 27, 2010. For the reasons set forth below, this Court affirms the Secretary's final decisions, as they were not arbitrary and capricious and were supported by substantial evidence. Accordingly, Plaintiff's Motion for Summary Judgment (Paper No. 39) is DENIED and Defendant's Motion for Summary Judgment (Paper No. 44) is GRANTED.

BACKGROUND

I. Coverage under the Medicare Statute

The Medicare program, a federally funded health insurance program for the aged and disabled, is set forth in Title XVIII of the Social Security Act, commonly referred to as the Medicare Act (the "Act"). 42 U.S.C. §§ 1395 *et seq*. The instant action involves Part B of the Act, which is a supplemental program that insures costs relating to various medical services, including the provision of durable medical equipment ("DME"). 42 U.S.C. §§ 1395k(a)(1), 1395x(n), 1395x(s), and 1395m(j)(5). The Act and its associated regulations provide that Medicare coverage extends to all items of DME except those deemed to be "experimental or investigational," 42 C.F.R. § 411.15(o), and "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

Medicare coverage is determined in one of three ways. The Secretary, through its Centers for Medicare and Medicaid Services ("CMS"),[1] may issue a binding national coverage determination ("NCD"), which reflects the Secretary's decision as to whether or not an item or service is covered nationally. 42 U.S.C. § 1395ff(f)(1)(B). Alternatively, a Medicare contractor may choose to issue a local coverage determination ("LCD"), stating that an item or service is covered in that particular contractor's jurisdiction. 42 U.S.C. § 1395ff(f)(2)(B). Finally, in instances where no NCD or LCD applies, individual coverage determinations may be made by Medicare contractors, which apply the "not reasonable and necessary" standard in the course of processing benefits claims. 68 Fed. Reg. 63692, 63693 (Nov. 7, 2003) (final rule).

II. Processing of DME Claims

[1] The Centers for Medicare and Medicaid Services ("CMS"), a component agency of the Department of Health and Human Services, administers the Medicare program.

To have a benefits claim processed, a DME supplier must timely provide a Medicare contractor with sufficient information to permit determinations regarding coverage and payment. 42 U.S.C. § 1395*l*(e); 42 C.F.R. § 424.5(a)(6). In addition, an electronic DME claim must include a Healthcare Common Procedure Coding System ("HCPCS") billing code. 45 C.F.R. §§ 162.1000(a), 162.1002(b)(3).

Medicare benefit claims are processed by administrative contractors, which are private insurance companies hired by the Secretary to perform various functions, including the provision of coverage and payment determinations in accordance with the Medicare statute and agency guidelines. 42 U.S.C. § 1395u; 42 C.F.R. §§ 405.803, 421.200. Claims by DME suppliers are submitted to jurisdiction-specific administrative contractors called DME Medicare Administrative Contractors ("DMACs") for processing. 42 U.S.C. § 1395u; 42 C.F.R. § 421.200. Each of the four geographic jurisdictions created by the Centers for Medicare and Medicaid Services ("CMS") has its own DMAC. 42 U.S.C. § 1395m(a)(12); 42 C.F.R. §§ 424.32, 421.210(b), 421.404(c)(2). If the DMAC determines that the DME item is covered or otherwise reimbursable under Medicare, it will furnish a payment amount that is equal to "80 percent of the lesser of . . . the actual charge for the item; [or] the fee schedule amount for the item." 42 C.F.R. § 414.210(a).

If a DME item is denied coverage under Medicare and "neither the beneficiary nor the supplier knew, or reasonably could have been expected to know, that the DME item would not be covered because of lack of medical necessity," Medicare often will still supply payment for the DME item. Pl.'s Statement of Material Facts ("SOMF") ¶ 9 (citing Medicare Claims Processing Manual ("MCPM") Ch. 30, § 20). On the other hand, if a beneficiary knows, or could be expected to know, that coverage will be denied for lack of medical necessity, the

beneficiary will generally be held liable for the claim. Pl.'s SOMF ¶ 9; 42 U.S.C. § 1395pp. In situations where the supplier is the sole entity with knowledge or constructive knowledge of an imminent coverage denial, the supplier must shoulder liability for its costs. 42 C.F.R. § 411.406(e).

Suppliers may provide beneficiaries with written "advance beneficiary notice" ("ABN") that states that Medicare will probably not cover or pay for a DME item because of a lack of medical necessity. When this written notice is supplied to the beneficiary, the beneficiary is liable for payment of the DME item. 42 C.F.R. § 411.404(b); MCPM Ch. 30, § 40.1.1. In the ABN, the supplier must state the potential reason for Medicare's denial of DME payment and must also declare the reason the supplier anticipates Medicare will not cover or pay for the DME. Pl.'s SOMF ¶ 10; MCPM Ch. 30, § 50.2.1. An ABN that simply states that Medicare might not pay for DME and fails to offer a reason for non-payment is called a "generic ABN." Pl.'s SOMF ¶ 10; MCPM Ch. 30, § 40.3.6.1. A generic ABN does not give adequate notice to a beneficiary of Medicare's potential denial of DME payment. MCPM Ch. 30, § 40.3.6.1.

III. The Medicare Appeals Process for DME Claims

A party dissatisfied with the decision of the DME Medicare Administrative Contractor ("DMAC") regarding a claim for Medicare's coverage or payment may request a "redetermination" by the same DMAC. 42 C.F.R. §§ 405.940-405.958; 42 U.S.C. § 1395ff(a)(3). The DMAC's redetermination process is non-adversarial, and its decision is non-precedential. 42 C.F.R. § 405.948. A party receiving a "redetermination" may seek further review by applying for a "reconsideration" by a qualified independent contractor ("QIC"). 42 C.F.R. § 405.960; 42 U.S.C. §§ 1395ff(b)(1)(A) and (C). If the QIC is tasked with reconsidering a finding on whether an item or service is medically reasonable and necessary, then the QIC

must consider input from a panel of physicians or other appropriate health care professionals. 42 C.F.R. §§ 405.968(a)(1) and (c)(3). The QIC's "reconsideration," which is non-precedential, may be further appealed to an Administrative Law Judge ("ALJ"). 42 C.F.R. §§ 405.1000-02; 42 U.S.C. §§ 1395ff(b)(1)(A), (E) and (d)(1). The ALJ's decision is similarly non-precedential and is required to be based on the evidence in the administrative record. 42 C.F.R. § 405.1046.

Finally, the ALJ's decision may be appealed to the Medicare Appeals Council ("MAC"), which is a division of the Department of Health and Human Services. The MAC reviews the administrative record and makes a decision based solely on those facts. 42 C.F.R. § 405.1122. The decision by the MAC constitutes the Secretary's final decision for purposes of judicial review. 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. § 405.1136.

IV. Bionicare's Claims for the BIO-1000

Plaintiff Monique D. Almy ("Plaintiff") is the Chapter 7 trustee for the bankruptcy estate of Bionicare Medical Technologies, Inc. ("Bionicare" or "Supplier"). From March 4, 2004, until the company filed for bankruptcy in 2007, Bionicare was enrolled in the Medicare program as a supplier of durable medical equipment ("DME"). It manufactured and distributed the Bionicare Stimulator System, Model 1000 ("BIO-1000"), which is used to treat osteoarthritis of the knee by delivering electrical pulses to the knee joint.

In 1997, Murray Electronics, the company from which Bionicare licensed the BIO-1000, provided the Food and Drug Administration ("FDA") with notification of its intent to distribute the BIO-1000 commercially, pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act. A.R. at 20755-58. In its notification, Murray Electronics stated that the BIO-1000 was "substantially equivalent" to the transcutaneous electric nerve stimulator ("TENS"), which was a predicate device already legally on the market. A.R. at 20756. Based upon its equivalence to the TENS, the FDA approved the BIO-1000 for marketing as a "Class II" device

in July 1997, to be used as an "adjunctive therapy . . . [for] reducing the level of pain and symptoms associated with osteoarthritis of the knee . . . ." A.R. at 306-08, 367-71.

The FDA reaffirmed its clearance of the BIO-1000 in 2003, and in 2006, the FDA decided that the BIO-1000 could also be used as an adjunctive therapy to reduce hand stiffness and pain associated with rheumatoid arthritis. A.R. at 309-10, 20765-67. CMS supplied the BIO-1000 with a Healthcare Common Procedure Coding System ("HCPCS") code, which became effective on January 1, 2006, and in April of 2006, CMS created a DME fee schedule for the device. A.R. at 314-15, 439-46.

BioniCare eventually distributed the BIO-1000 to Medicare patients, and Plaintiff contends that "tens of thousands" of BioniCare's claims have been granted coverage. Pl.'s SOMF ¶ 21. Nevertheless, Medicare contractors have also denied many claims relating to the item. Many of Bionicare's claims were subsequently pursued up the administrative ladder of appeals to the Medicare Appeals Council ("MAC"). In seven distinct groups of MAC decisions, the Secretary determined that the BIO-1000 was not "medically reasonable and necessary," and rejected the relevant claims for coverage. In the eighth appeal ("the 191 Decision"), the Secretary's analysis was limited to the issue of determining payment for nine separate claims. In the 191 Decision, the MAC affirmed a payment calculation for the claims in a ruling that was deemed to be unfavorable to Bionicare. *Id.* The following groups of decisions, listed by their ALJ Appeal Numbers, are at issue in this case:

ALJ Appeal Number(s)	**"Known collectively as…"**	**Date issued**
1-195779535; 1-180164901; 1-201743101	"the 535 Decision"	April 11, 2008
1-123891310	"the 310 Decision"	March 7, 2008
1-18738208	"the 208 Decision"	March 11, 2008
1-47735891	"the 891 Decision"	March 13, 2008
1-41464852; 1-85869975; 1-52083943; 1-85881348; 1-85869521; 1-85870420;	"the 852 Decision"	March 11, 2008

1-85870179; 1-85881284		
1-52581259	"the 259 Decision"	March 11, 2008
1-86962781	"the 781 Decision"	April 9, 2008
1-182560191	"the 191 Decision"	March 25, 2008

See Pl.'s SOMF ¶ 20.

On May 12, 2008, Plaintiff Monique D. Almy filed the present lawsuit against the Secretary of the United States Department of Health and Human Services, requesting judicial review of the final MAC decisions listed above. Plaintiff seeks a ruling from this Court reversing these decisions and instructing the Secretary to pay the claims at issue in accordance with Medicare law.

STANDARD OF REVIEW

The Medicare statute provides that judicial review of a final decision of the Secretary "is to be based solely on the administrative record, and the Secretary's findings of fact, if supported by substantial evidence, shall be conclusive." *MacKenzie Med. Supply, Inc. v. Leavitt*, 506 F.3d 341, 346 (4th Cir. 2007) (citing 42 U.S.C. § 1395ff(b)(1)(A) and 42 U.S.C. § 405(g)). In addition, judicial review of the Secretary's decision is governed by the Administrative Procedure Act ("APA"), which provides that final agency action shall be upheld absent a finding that it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; . . . without observance of procedure required by law" or is "unsupported by substantial evidence in a case." 5 U.S.C. §§ 706(2)(A), (D), and (E).

The arbitrary and capricious standard requires a reviewing court to consider whether the agency:

> relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Vehicle Mfrs. Ass'n. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). This is a "highly deferential standard which presumes the validity of the agency's action," *Natural Resources Defense Council v. EPA*, 16 F.3d 1395, 1400 (4th Cir. 1993), and an agency's decision should only be overruled upon a finding that the agency has "failed to consider relevant factors and committed a clear error of judgment." *Md. Dep't of Health & Mental Hygiene v. Ctrs. for Medicare & Medicaid Servs.*, 542 F.3d 424, 428 (4th Cir. 2008) (citation omitted).

Substantial evidence has been defined as "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion" and it is measured to be "more than a mere scintilla of evidence but may be somewhat less than a preponderance." *Mastro v. Apfel*, 270 F.3d 171, 176 (4th Cir. 2001) (internal citations omitted). Under this narrow standard of review, a court is not supposed to weigh the evidence, make findings of fact, or resolve conflicts in the record. Thus, it is not "the court's function to substitute its judgment for that of the Secretary if his decision is supported by substantial evidence." *Hays v. Sullivan*, 907 F.2d 1453, 1456 (4th Cir. 1990). Instead, the district court need only determine whether the quantity and quality of the evidence is sufficient so that a reasonable mind might find it adequate to support the Secretary's decision.

"In addition, to the extent HHS has based its decision on the language of the Medicare Act itself, we owe deference under *Chevron U.S.A. Inc. v. Natural Resources Defense Council,* 467 U.S. 837, 843-45 (1984)." *Marymount Hosp., Inc. v. Shalala*, 19 F.3d 658, 661 (D.C. Cir. 1994). Under the *Chevron* two-step framework, courts first determine whether Congress has directly addressed the "precise question at issue," and if it has, "the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." 467 U.S. at 842-43. However, if the statute is silent or ambiguous with respect to the specific issue, the court then

must assess "whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843. With regard to this second step, an agency's interpretation of a statute "need not be the best or most natural one by grammatical or other standards . . . Rather [it] need be only reasonable to warrant deference." *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 702 (1991) (citations omitted); *see also Bridgestone/Firestone, Inc. v. Pension Ben. Guaranty Corp.*, 892 F.2d 105, 110 (D.C. Cir. 1989) ("[a]s long as the agency's [construction of the statute is] consistent with the language and purpose of the statute, [the Court] must defer to the agency's interpretation").

Finally, the decision of the Secretary must be viewed in light of the fact that "where Congress has made an explicit or implicit grant of power to an agency over certain matters, [such as review of claims arising under the Medicare Act], that grant of power embodies congressional recognition of the agency's 'special competence' to handle those matters, and compels deference from the courts in reviewing how that power is exercised." *National Fuel Gas Supply Corp. v. FERC*, 811 F.2d 1563, 1569-70 (D.C. Cir. 1986) (citing *Chevron*, 467 U.S. at 843-44). Indeed, "deference to the Secretary's interpretations of Medicare regulations is 'all the more warranted,' because Medicare 'is a complex and highly technical regulatory program, in which the identification and classification of relevant criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns.'" *Dist. Mem'l Hosp. of Southwestern N.C. v. Thompson*, 364 F.3d 513, 518 (4th Cir. 2004) (quoting *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994)).

DISCUSSION

In seven of the eight final decisions of the Medicare Appeals Council at issue in this case, the Secretary denied Medicare coverage for the BIO-1000 because it was determined to be not

reasonable and necessary for the treatment of osteoarthritis of the knee. In the eighth decision, the Secretary upheld a Medicare contractor's payment determination for nine claims in a ruling that was considered unfavorable to Bionicare. These decisions are challenged as arbitrary and capricious and as otherwise unsupported by substantial evidence. Plaintiff claims that in the coverage decisions the Secretary rendered interpretations that contradicted the agency's prior decisions and interpretations. In addition, Plaintiff claims that the Secretary's decisions are substantively incorrect and contrary to the view held by the medical community and the FDA, which have allegedly sanctioned the BIO-1000 as medically "reasonable and necessary."

I. Whether the Secretary's Final Coverage Decisions Were Inconsistent with the Agency's Prior Decisions and Interpretations

The Supreme Court has noted that "[t]he Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions." *Heckler v. Ringer*, 466 U.S. 602, 617 (1984). Thus, as a general matter, the Secretary's formal case adjudications concerning Medicare payment and coverage, which involve an application and interpretation of the "reasonable and necessary" provision in the Medicare Act, must be afforded substantial deference, absent a showing that they are arbitrary and capricious, or unsupported by substantial evidence.[2] *See*

[2] This Court rejects Plaintiff's unsupported contention that the deference owed to the Secretary's final decisions must be vastly reduced in part because they were not preceded by any statute, regulation, or policy addressing the BIO-1000. Pl.'s Opp. at 6. Courts consistently defer to the Secretary in recognition of her broad statutory authority over Medicare coverage matters, and formal case adjudications represent a proper exercise of that authority. *See Heckler v. Ringer*, 466 U.S. 602, 617 (1984). Plaintiff's argument would restrict agency decision-making by effectively requiring the Secretary to issue item-specific coverage rules for each and every item of DME before issuing case adjudications. *See West Virginia v. Thompson*, 475 F.3d 204, 210 (4th Cir. 2007) ("Agencies are ordinarily permitted to choose in adjudication among permissible meanings of statutes they are charged with administering, without spelling out their interpretations beforehand through notice-and-comment rulemaking").

United States v. Mead Corp., 533 U.S. 218, 230 (2001) ("Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force. Thus, the overwhelming number of our cases applying *Chevron* deference have reviewed the fruits of notice-and-comment rulemaking or formal adjudication.") (internal citations omitted). Plaintiff maintains, however, that deference is not warranted in this case because the final decisions issued by the MAC mark an unexplained departure from the Secretary's prior decisions and interpretations relating to coverage for the device.

A. Alleged Inconsistency with Prior Coverage Decisions

Plaintiff claims that the Secretary's final decisions are inexplicably inconsistent with thousands of favorable coverage determinations relating to the BIO-1000. Such inconsistency, it is urged, exposes the Secretary's interpretation of the Medicare statute and her application of that interpretation to the present claims as arbitrary and capricious. *See Nat'l Cable & Telecomm. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005) ("Unexplained inconsistency is, at most, a reason for holding an interpretation to be an arbitrary and capricious change from agency practice under the Administrative Procedure Act"); *Bush-Quayle '92 Primary Comm., Inc. v. FEC*, 104 F.3d 448, 453 (D.C. Cir. 1997) (noting that "[a]n agency interpretation that would otherwise be permissible is, nevertheless, prohibited when the agency has failed to explain its departure from prior precedent").

In support of its argument, Plaintiff points to the recent decision of the U.S. District Court for the Western District of Washington reversing four final decisions of the Secretary denying Medicare coverage for the BIO-1000. *International Rehabilitative Sciences, Inc., v. Sebelius*, 2010 U.S. Dist. LEXIS 86222 (W.D. Wash. July 28, 2010). This case addressed claims related to a participating distributor for the BIO-1000, International Rehabilitative Sciences, and

addresses many of the same issues that exist in the case at bar. The court in *International Rehabilitative Sciences* determined that the MAC decisions denying coverage were arbitrary and capricious primarily because they were inconsistent with prior favorable coverage decisions made by subordinate contractors and ALJs.

This Court recognizes that the deference normally afforded to an agency interpretation is weakened where it is found to be inconsistent with a prior agency position. *See, e.g., Malcomb v. Island Creek Coal Co.*, 15 F.3d 364, 369 (4th Cir. 1994) ("When the agency's varying interpretations of a regulation have not been the result of the agency making considered changes in its policy, but rather of the agency simply acting inconsistently without explanation . . . 'the case for judicial deference is less compelling'") (quoting *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 698 (1991)); *Bankamerica Corp. v. United States*, 462 U.S. 122, 130-32 (1983) (finding that agencies' interpretation of a statute that reversed their prior interpretation of sixty years was not entitled to deference). However, the Secretary's final coverage decisions at issue in this case are not arbitrary and capricious because they do not represent any material inconsistency. This Court respectfully disagrees with the opinion of the U.S. District Court for the Western District of Washington in *International Rehabilitative Sciences.* Specifically, this Court disagrees with the notion that the non-binding, non-precedential rulings of lower-level contractors may together constitute an authoritative agency interpretation directly attributable to the Secretary. Thus, this Court holds that through the decisions of its Medicare Appeals Council, the Secretary legitimately announced her interpretation of the BIO-1000 as not medically reasonable and necessary.

The record reflects that a great many claims relating to the BIO-1000 have been processed by Medicare contractors. Initially, in 2004 and 2005, the overwhelming majority of

Medicare claims relating to the device were denied. (A.R. 24197-24200.) However, after a unique set of billing codes for the BIO-1000 became effective in 2006, an increasing number of claims began to receive favorable treatment. Although the parties dispute exact numbers, the record indicates that after 2006, the vast majority of claims were approved. (A.R. 375, 377.) In addition, it is clear that several claims, which had been appealed, had been confirmed in favorable decisions issued by administrative law judges.

Given the vast number of Medicare claims processed by contractors under the Medicare system,[3] it is understandable that variation may result in payment and coverage decisions for a particular item of DME. Nevertheless, it is undisputed that lower-level decisions rendered by contractors and ALJs are non-precedential. *See* Pl.'s SOMF at ¶¶ 12, 13, 15 (citing 42 C.F.R. §§ 405.948; 405.968; 405.1046). Therefore, when the MAC addresses a Medicare case on appeal from an ALJ, it is not bound in any way by the reasoning or conclusions of its subordinate decision-makers. The MAC undertakes a *de novo* review of all the evidence in the record, and may modify, affirm, or reverse the ALJ's decision, or remand the case to the ALJ. 42 C.F.R. § 405.1100(c). The Medicare Appeals Council is a division of the Department of Health and Human Services and its determinations are directly attributable to the Secretary and are binding on all parties. 42 C.F.R. § 405.1130. This leads to the conclusion that the Secretary's final decisions, as rendered by the MAC, cannot be faulted for conflicting with its subordinates' findings; indeed, the Medicare appeals process was specifically designed to allow for this result.

It comes as no surprise that the thrust and implications of Plaintiff's argument—that lower level decision-makers in a massive and hierarchical administrative appeals system may bind the Secretary—has been squarely rejected in related settings. For instance, the District of

[3] The government has noted that in 2004, carriers processed 772 million Part B claims and that DME benefits totaled $7.783 billion, or 6.1% of Part B benefits. Def.'s Mot. for Summ. J. at 39.

Columbia Circuit addressed a challenge to the Secretary's reimbursement determination on the basis that it conflicted with a prior decision of the subordinate Provider Reimbursement Review Board ("PRRB"). The court explained that this apparent inconsistency did not make the Secretary's decision arbitrary and capricious:

> There is no authority for the proposition that a lower component of a government agency may bind the decision making of the highest level. As we held in *Amor Family Broadcasting Group v. FCC*, 287 U.S. App. D.C. 20, 918 F.2d 960 (D.C. Cir. 1991), "even if these cases were found to evince internal inconsistency at a subordinate level, the [agency] itself would not be acting inconsistently." 918 F.2d at 962.

Community Care Found. v. Thompson, 318 F.3d 219, 227 (D.C. Cir. 2003). The Seventh Circuit voiced similar points when it held that the decision of the Secretary's delegate was not impermissible merely because it conflicted with lower-level decision-makers:

> [T]he Department of Health and Human Services is a mammoth bureaucracy with seemingly endless layers of internal review . . . "The Secretary's position" is the position of the Department as an entity, and the fact that people in the chain of command have expressed divergent views does not diminish the effect of the agency's resolution of those disputes. An inconsistent administrative position means flip-flops by the agency over time, rather than reversals within the bureaucratic pyramid.

Homemakers North Shore, Inc. v. Bowen, 832 F.2d 408, 413 (7th Cir. 1987) (citations omitted). *See also, e.g.*, *St. Luke's Hospital v. Sebelius*, 2010 U.S. App. LEXIS 13701, at *21 n.10 (D.C. Cir. July 6, 2010) (noting that decisions by the PRRB, a lower agency decisional body, "do not bind CMS or the Secretary"); *St. Francis Hospital Center v. Heckler*, 714 F.2d 872, 874 (7th Cir. 1983) ("Final responsibility for rendering a decision lies in the agency itself, not with subordinate hearing officers. . . . The decision of the PRRB can be considered no more expert than the decision of the Secretary") (internal citations omitted); *Homan & Crimen, Inc. v. Harris*, 626 F.2d 1201, 1205 (5th Cir. 1980) ("the decision of the PRRB carries no more weight on

review by the Secretary than any other interim decision made along the way in an agency where the ultimate decision of the agency is controlling").

The Plaintiff's argument, which was accepted by the court in *International Rehabilitative Sciences*, inverts the carefully crafted Medicare appeals process and invites unintended results. Payment determinations by lower-level components could assume precedential status and effectively bind the MAC, a superior decisional body with delegated authority from the Secretary. Such a scenario is not prescribed by the statutory text and regulations and would subvert the proper functioning and design of the system. MACs that did not defer to administrative subordinates would become especially vulnerable to challenge in federal court, leading in turn to increased litigation and uncertainty and threatening finality in the Medicare appeals process. Moreover, Plaintiff's position portends to undermine the Secretary's position as the ultimate arbiter of the Medicare program, which is protected and ensured by the APA. *See Thomas Jefferson Univ.*, 512 U.S. at 512; *Dist. Mem'l Hosp. of Southwestern N.C.*, 364 F.3d at 518.

In *International Rehabilitative Sciences*, the court reasoned that the Secretary "has the tools available to shore up inconsistency throughout the coverage system," and that she could have issued a national coverage determination ("NCD"). 2010 U.S. Dist. LEXIS 86222, at *19. As a prudential matter, the issuance of a NCD may, in certain circumstances, benefit involved parties by affording clear coverage guidance on a particular DME. However, the position expressed in *International Rehabilitative Sciences* would impose a *de facto* requirement—not envisioned in the statute or regulations—upon the Secretary to issue an NCD in these situations. This is antithetical to the design of the Medicare program, which affords the Secretary substantial leeway in deciding whether to administrate the system through generally applicable

coverage rules and policies or through adjudication. *See Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 96-97 (1995) ("The Secretary's mode of determining benefits by both rulemaking and adjudication is, in our view, a proper exercise of her statutory mandate"); *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947) ("[T]he choice made between proceeding by general rule or by individual, *ad hoc* litigation is one that lies primarily in the informed discretion of the administrative agency"). Such discretion serves a practical purpose, as the Secretary cannot rightfully be expected to preemptively issue NCDs for each and every DME to forestall inevitable inconsistencies among lower-level components in the administrative appeals system.

B. Alleged Inconsistency with the Agency's Prior Coverage Interpretation

On a related note, Plaintiff argues that the MAC's coverage decisions announced a new legal standard that substantially departs from the agency's prior coverage interpretation for the BIO-1000. Plaintiff maintains that the decisions are arbitrary and capricious and not entitled to deference because they were not promulgated pursuant to the APA's notice and comment requirements. Pl.'s Opp. at 23-24 & n.23 (citing *Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 629 (5th Cir. 2001) (requiring "an agency to provide an opportunity for notice and comment before substantially altering a well established regulatory interpretation"); *Alaska Professional Hunters Ass'n v. FAA*, 177 F.3d 1030, 1034 (D.C. Cir. 1999) ("When an agency has given its regulation a definitive interpretation, and later significantly revises that interpretation, the agency has in effect amended its rule, something it may not accomplish without notice and comment")).

Plaintiff's line of argument, which was explicated by the Fifth Circuit in *Shell Offshore, Inc. v. Babbitt*, 238 F3d 622 (5th Cir. 2001), has not been embraced by the Fourth Circuit.[4] *See Chen Zhou Chai v. Carroll*, 48 F.3d 1331, 1340-41 (4th Cir. 1995) (concluding that agency could

[4] Plaintiff's argument is also based upon the decisions of the District of Columbia Circuit in *Alaska Prof'l Hunters Ass'n v. FAA*, 177 F.3d 1030 (D.C. Cir. 1999) and *Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579 (D.C. Cir. 1997). *See* Pl.'s Opp. at 24 n.23.

amend or revoke a prior agency interpretation by promulgating an interpretative rule without notice and comment). Furthermore, such an approach would have no currency in the present case. Even assuming, *arguendo*, that the final decisions represent an authoritative legal standard,[5] it cannot be viewed as conflicting with any prior definitive and unambiguous interpretation of the Secretary.

The record reflects that the Medicare claims for the BIO-1000 have produced various coverage decisions at the lower levels of the appeals system. It is difficult to see how these decisions could be viewed as promoting a cohesive interpretation, let alone an authoritative one. As noted above, it is well-established that lower-level contractors and ALJs cannot speak on behalf of the Secretary. *See, e.g.*, *Willowood of Great Barrington, Inc. v. Sebelius*, 638 F. Supp. 2d 98, 113-14 (D. Mass. 2009) ("Plaintiffs fail to demonstrate how an administrative law judge's *decision* can morph into an agency's rule *standard*. They certainly cite no case law to that effect") (emphasis in original); *Monongahela Valley Hosp. v. Sullivan*, 945 F.2d 576, 589 (3d Cir. 1991) (noting that it is unreasonable to rely upon the decision made by a fiscal intermediary, which "can neither definitively interpret regulations nor make policy pronouncements" on behalf of the Secretary). *See also Devon Energy Corp. v. Kempthorne*, 551 F.3d 1030, 1040 (D.C. Cir. 2008) (stating that "a definitive and binding statement on behalf of the agency must come from a source with the authority to bind the agency").

[5] Notice and comment rulemaking is only required for: (1) a "rule, requirement, or other statement of policy" that (2) "establishes or changes a substantive legal standard governing the scope of benefits [or] the payment for services." 42 U.S.C. § 1395hh(a)(2). The Secretary contends that its "final decisions, reached in eight case adjudications, are plainly not the type of agency action addressed by § 13955hh(a)(2)." Def.'s Mot. Summ. J. at 13. This Court need not resolve whether the final decisions establish a substantive legal standard, as it finds that Plaintiff's argument fails on separate grounds.

In the meantime, as discrepancies developed among the lower-level decision-makers, the Secretary took no initiative to affirmatively announce an interpretation. As Plaintiff has observed, the "Secretary has not adopted a regulation, NCD, or interpretive manual (or policy) specifically addressing the BIO-1000." Pl.'s Opp. at 25. Prior to the issuance of the MAC decisions in this case, there was no clear and authoritative interpretation regarding coverage for the BIO-1000 that the Plaintiff could have justifiably relied upon. *See Devon Energy Corp.*, 551 F.3d at 1041 (rejecting reliance claim and noting that guidance documents did not rise to authoritative interpretation because they were "far from conclusive in what they said" and "did not come from sources who had the authority to bind the agency"). As a result, this Court finds that the MAC decisions need not have been subjected to the notice and comment process because they did not conflict with any pre-existing "well-established, definitive, and authoritative interpretation" of the Secretary.[6] *Warshauer v. Solis*, 577 F.3d 1330, 1338 (11th Cir. 2009).

II. Whether the Secretary's Coverage Decisions Are Substantively Valid

Plaintiff challenges the substantive correctness of the Secretary's decisions relating to the BIO-1000. In arriving at its coverage denials, the Secretary relied upon the Medicare Act's general coverage exclusion for devices that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).[7] Plaintiff contends that the Secretary's decisions were not based upon

[6] Even if the Secretary's decisions were understood to be inconsistent with prior interpretations, this Court would not be prohibited from deferring to them to some degree. Deference is not an all-or-nothing proposition. *See United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) ("the weight [accorded to an administrative] judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control") (internal quotation marks omitted).

[7] In addition, the Medicare regulations further exclude coverage for "experimental or investigational devices." 42 C.F.R. § 411.15(o). The term "reasonable and necessary" has been

substantial evidence because they failed to properly account for the BIO-1000's status as an FDA-cleared device that has been accepted and approved by the general medical community.

Because Plaintiff has failed to establish any material inconsistency on the part of Secretary, this Court proceeds to assess the validity of the Secretary's final decisions under the normal deferential standard of review.[8] As indicated above, substantial evidence has been defined as "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Richardson v. Perales*, 402 U.S. 389, 401 (1971) (internal quotations omitted). In determining whether the Secretary's decisions are supported by substantial evidence, judicial review must be "searching and careful," but at the same time, this Court "must not substitute its judgment for that of the agency." *Blaustein & Reich, Inc. v. Buckles*, 365 F.3d 281, 291 (4th Cir. 2004). *See also Apollo Medical, Inc. v. Sebelius*, 2010 U.S. Dist. LEXIS 52452, at *21 (E.D. Mo. Apr. 23, 2010) ("Even if there is substantial evidence that would support a decision opposite to that of the Secretary, the court must affirm her decision as long as there is substantial evidence in favor of the Secretary's position.").

A. Precedential Effect of FDA Clearance

Plaintiff claims that the MAC's decisions failed to properly recognize and appreciate the significance of the Food and Drug Administration's approval of the BIO-1000. On three

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interpreted by the Secretary to mean "safe and effective," "not experimental or investigational," and "appropriate." Medicare Program Integrity Manual, Ch. 13, § 13.5.1.

[8] In *International Rehabilitative Sciences*, the court determined that it was reviewing an exceptional case, involving "egregious and unexplained" agency inconsistency, in which no deference was warranted. 2010 U.S. Dist. LEXIS 86222, at *20-21 ("this appears to be one of those 'rare instances' [in which] the Secretary's decisions are entitled to no deference"). Consequently, in assessing the substantive correctness of Secretary's unfavorable coverage findings, the court essentially re-analyzed the findings and evidence *de novo*. *Id.* at *22 ("the Secretary has offered two clearly conflicting characterizations . . . in order to resolve the conflict, the Court will review the Secretary's characterizations side by side, so that it may sustain one and reject the other"). In this case, however, the Secretary's decisions must be reviewed with deference because they were not found to involve any inconsistency.

separate occasions, the FDA granted the BIO-1000 market clearance under Section 510(k) of the Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FFDCA"). In so doing, the BIO-1000 was determined to be "substantially equivalent" to the transcutaneous electric nerve stimulator ("TENS") device that was marketed before the MDA took effect in 1976. The BIO-1000 was not, however, cleared under the FDA's separate and more exacting "premarket approval" process, which "includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-18 (2008) (distinguishing the premarket approval process as more "rigorous" than the § 510(k) process); *see also PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 925 n.3 (9th Cir. 2010) ("[u]nlike premarket approval, 510(k) clearance 'does not in any way denote official approval of the device'") (quoting 21 C.F.R. § 807.97).

FDA clearance or approval—particularly of the form provided under § 510(k)—does not automatically guarantee Medicare coverage, as the FDA and the CMS are independent entities with different agendas and statutory mandates. *See Goodman v. Sullivan*, 891 F.2d 449, 451 (2d Cir. 1989). Instead, FDA approval is considered a necessary, but not sufficient, factor for purposes of determining Medicare coverage. *See* 42 C.F.R. § 405.201(a)(1) ("CMS uses the FDA categorization of a device as a factor in making Medicare coverage determinations."); *see also* 68 Fed. Reg. 55634, 55636 (Sept. 26, 2003) ("[a]lthough an FDA-regulated product must receive FDA approval or clearance . . . for at least one indication to be eligible for Medicare coverage, . . . FDA approval/clearance alone does not generally entitle that device to Medicare coverage").

In assessing whether Medicare coverage was warranted, the MAC properly recognized that the BIO-1000 had obtained FDA clearance under § 510(k). The Secretary explained that

according to applicable regulations, FDA approval is a prerequisite for Medicare coverage, but not a guarantee. (A.R. 13-15, 32-34, 52-54, 15789-90, 15814-15, 20667-68, 23356-57.) It was observed that the BIO-1000 had received clearance for marketing, but had never been subjected to the more rigorous standards of premarket approval. *See, e.g.*, A.R. 20668. Finally, the Secretary affirmed a decision of one of the ALJs, which further discounted the significance of the BIO-1000's clearance because Bionicare had given conflicting representations concerning its equivalence to the TENS device. While the BIO-1000's marketing clearance was predicated upon its alleged similarity to the TENS device, the company repeatedly emphasized during the Medicare appeals process that the two devices are distinguishable in several respects, including their methods of operation and the medical conditions they target. *See, e.g.*, A.R. 13, 15792. *See also Svidler v. U.S. Dep't of Health & Human Servs.*, 2004 U.S. Dist. LEXIS 18325, at *9-17 (N.D. Cal. June 10, 2004) (affirming coverage denial for device that was originally cleared based on substantial equivalence with a TENS device, but was later used for services not ascribed to the TENS device).

Contrary to Plaintiff's contention, the Secretary's final decisions reveal a thorough consideration of the BIO-1000's status as a FDA-cleared device. Discerning attention was paid to applicable regulations, the difference between FDA approval and Medicare coverage, and the significance of market clearance versus premarket approval.

B. Evidence Relating to Medical Efficacy

Plaintiff also claims that the Secretary's final decisions fail to appreciate that the BIO-1000 has been accepted by the general medical community, as evidenced in peer-reviewed publications, statements of treating physicians and independent medical experts, letters of medical necessity ("LMNs"), and animal and electromagnetic studies. Consistent with this receptive treatment, a unique HCPCS code and two fee schedule payment amounts have been

assigned to the device. This underlying support, Plaintiff maintains, is uncontroverted in the record, and militates for a finding that the device is reasonable and medically necessary and not experimental or investigational. Finally, Plaintiff argues that it is not clear whether some of the QICs incorporated the medical review mandated by the Medicare regulations when assessing the subject claims.

The Secretary's final decisions denying coverage paid sufficient attention to medical factors and Plaintiff has not identified any fatal deficiency in this respect. In reviewing the Plaintiff's submissions, the Secretary cited applicable criteria set forth in sections 13.5.1 and 13.7.1 of the Medicare Program Integrity Manual ("MPIM"), which properly apply in making coverage determinations. *See, e.g.*, A.R. 11-14, 15788-89. With these factors in mind, the Secretary observed that many of Bionicare's submissions were produced or supported by biased sources, such as employees and officers of Bionicare and Murray Electronics. A.R. 378-82, 384-89, 423-38, 506-11, 20914-19, 33851-75, 33917-44. In addition, the Secretary found serious methodological shortcomings in some of the submissions, which referenced studies based on very small sample sizes and short time frames. *See, e.g.*, A.R. 380, 386, 431, 507. Some of the submissions cited "magnetic pulse" studies that obtained inconclusive results and announced the need for further investigation. A.R. 397-99, 22728, 33876-82. The Secretary properly minimized the persuasive weight of these submissions in compliance with MPIM § 13.7.1, which provides that "limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community." Finally, it was observed that Bionicare attempted to rely upon four documents that did not comply with the peer-review requirement set forth in MPIM § 13.7.1. *See* A.R. 384-89, 24786-01, 33851-75,

33917-45. Therefore, the Secretary had proper cause to discount the significance of these articles.[9]

Plaintiff notes that the record contains twenty affidavits from independent treating physicians who claim that the BIO-1000 is reasonable and medically necessary for patients with osteoarthritis of the knee. *See* Pl.'s SOMF ¶ 57. However, these affidavits are of questionable significance, as they are standardized in format and include identical boilerplate language. Moreover, there is no support for notion that twenty standard form affidavits necessarily represent a general consensus in the medical community. *See MacKenzie Med. Supply, Inc.*, 506 F.3d at 348 (affirming Secretary's view that a similar standard form "certificate of medical necessity" is not always sufficient to entitle a DME supplier to reimbursement). Likewise, the physician "letters of necessity" touted by the Plaintiff do not substantially contribute to a finding of medical necessity. These "statements" constitute brief sections on Bionicare-capitioned prescription forms and contain basic patient information in "check-the-box" format.[10] *See, e.g.*, A.R. 627, 661, 1440, 1611. Finally, it was similarly reasonable for the Secretary to disavow any reliance on the animal studies submitted by Bionicare. These studies concern the effect of the BIO-1000 on animal tissue, but do not draw any conclusions about whether the device alleviates symptoms relating to osteoarthritis of the human knee. *See* A.R. 15793 ("animal studies have no probative value in determining whether the BIO-1000 meets Medicare medical necessity standards").

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[9] The deficiencies in Bionicare's submissions were also reported by six commercial insurers that categorically denied coverage for the BIO-1000. Def.'s Ex. 1 at 2-3, 5-7, 17.

[10] On a related note, Plaintiff cites the "treating physician's rule," which provides that a physician's determination of medical necessity cannot be rejected unless it is unsupported in the medical record and is not otherwise contradicted. This "rule," which was formulated by the Second Circuit for application in Social Security disability cases, "has never been extended to apply to Medicare coverage decisions." *Diapulse Corp. of Am. v. Sebelius*, 2010 U.S. Dist. LEXIS 25003, *23-24 (E.D.N.Y. Jan. 21, 2010).

CMS granted the BIO-1000 a HCPCS Level II billing code that became effective on January 1, 2006. A.R. 314-15. However, Plaintiff fails to establish that the assignment of such a code necessitates a favorable coverage determination. The billing code serves the purpose of facilitating the uniform reporting and processing of claims, but it has no bearing on the question of whether a device is found to be reasonable and necessary. Indeed, the introduction to the HCPCS code book contains a disclaimer notifying that "[i]nclusion or exclusion of a procedure, supply, product or service does not imply any health insurance coverage or reimbursement policy." Def.'s Ex. D. Likewise, the fee schedule payment amount that was assigned to the BIO-1000 is of little consequence, as the CMS' online fee schedule also includes a disclaimer stating that "[i]nclusion or exclusion of a fee schedule for an item or service does not imply any health insurance coverage." Def.'s Ex. P.

Finally, Plaintiff gains no traction with his claim that the QICs failed to incorporate the medical review required under the Medicare regulations. If a QIC's "reconsideration" involves an assessment of whether an item or service is medically reasonable and necessary under 42 U.S.C. § 1395y(a)(1)(A), then the QIC must consider input from a panel of physicians or other "appropriate health care professionals." 42 C.F.R. § 405.968(a). The QIC must also include a physician when the reasonable and necessary inquiry involves an item provided by a physician. *Id.* § 405.968(c)(3). However, there is no requirement that the physician review be documented. Instead, the QIC's notice of reconsideration need only include an explanation of the medical and scientific rationale for the decision. In this case, Plaintiff has not substantiated its claim that the QIC's reconsideration lacked the necessary medical review. In the absence of such an affirmative showing, there is no basis for this Court to presume that the QICs failed to utilize medical review in reaching their "reconsiderations." *See United States Postal Serv. v. Gregory*,

534 U.S. 1, 10 (2001) ("[A] presumption of regularity attaches to the actions of government agencies . . . .").

At bottom, this Court finds that the Secretary properly assessed the evidence in the record when it determined that Bionicare failed to establish the BIO-1000 as medically reasonable and necessary.

III. Challenge to the Secretary's Payment Decision (the "191 Decision")

In addition to the seven coverage decisions, Plaintiff challenges the MAC's decision relating to ALJ Appeal Number 1-182560191 (the "191 Decision"), which upheld a Medicare contractor's payment amounts for nine BIO-1000 claims. A.R. 20225, 20231. Plaintiff contends that the payment calculations in this final decision were improperly based upon an alleged "local fee schedule" amount. Plaintiff claims that Bionicare was instead owed a payment equal to 80 percent of its charges because the claims at issue arose before the Secretary published a fee schedule amount for the device on June 8, 2007. Pl.'s Opp. 8, 29 (citing 42 C.F.R. § 414.210(a)). Finally, this decision is construed to be arbitrary and capricious because it allegedly conflicts with other MAC decisions and is internally inconsistent.

The Medicare Act provides that a DME payment should be calculated as 80 percent of the lesser of (1) the actual charge for the item, or (2) the fee schedule amount determined by the payment methodology for DME with certain adjustments. 42 U.S.C. § 1395m(i); C.F.R. § 414.210(a). Because the subject claims arose before the Secretary's adoption of a fee schedule payment amount for the BIO-1000, the contractor proceeded by establishing a local fee schedule payment amount for the device, and paying 80 percent of this amount (which was less than 80 percent of Bionicare's actual charges for the device). A.R. 24332, 24348, 24351. In the absence of a national fee schedule amount for the BIO-1000, the contractor properly complied with generally applicable manual instructions requiring contractors to develop local fee schedule

amounts as a gap-filling methodology. *See* Medicare Claims Processing Manual ("MCPM"), ch. 20, § 20; MCPM ch. 23, § 60.3. Accordingly, the MAC's affirmation of the contractor's payment decision in the 191 Decision was "based on a consideration of the relevant factors" and does not include a "clear error of judgment." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Furthermore, the 191 Decision, which was limited to the issue of payment, does not in any way contravene the remaining seven final decisions, which concerned the separate issue of coverage. A.R. 20228-30. This Court also disagrees with Plaintiff's claim that the 191 Decision sanctioned "wide payment variations" in the claims under review. Pl.'s Mot. Summ. J. at 38. The Secretary recognized certain payment differences and explained that they were either insignificant or justified. The variations in the "Amount Paid" for each of the nine claims were "primarily attributable to the application of Beneficiary co-payments and deductibles." A.R. 20246. As to variations in the allowed amount figures, the Secretary found them to be "systematic—not random," and noted that the numbers differed by no more than $4.20 and varied only according to the beneficiary's state and residency. A.R. 20228, 20246.

IV. Challenge to the Secretary's Rejection of Certain Advance Beneficiary Notices ("ABNs")

The Medicare Act contains, in § 1395pp(a), a "waiver of liability" for certain denials of coverage, which may shield suppliers and/or beneficiaries from liability if "the individual beneficiary of the DME at issue and the DME supplier both 'did not know, and could not reasonably have been expected to know that payment would not be made for such items . . . .'" *MacKenzie Med. Supply*, 506 F.3d at 349 (quoting 42 U.S.C. § 1395pp(a)). However, under certain circumstances, a beneficiary may alone be held liable for a non-covered device if it receives from the supplier a written "advance beneficiary notice" ("ABN") providing notice that

coverage for the device will probably be denied due to a lack of medical necessity. To ensure that liability for a non-covered item is shifted to a beneficiary, the supplier's ABN must supply enough information for the beneficiary to understand the basis for a potential denial of coverage. 42 C.F.R. § 411.404; MCPM Ch. 30, § 40.1.1. However, if an ABN is deemed to be "generic," or if it fails to otherwise provide adequate notice, the beneficiary will be shielded, and liability for the uncovered item may instead rest with the supplier. MCPM Ch. 30, § 40.3.6.1.

In two of the eight decisions at issue in this case, the Secretary ruled that certain ABNs concerning the BIO-1000 were generic and therefore improper. A.R. 15785 ("535 Decision"); A.R. 20669-70 ("781 Decision"). The following ABN language was deemed insufficient:

> The [BIO-1000] is not the subject of either an affirmative coverage or non-coverage Medicare policy. Accordingly, it is unclear what criteria Medicare will use when evaluating whether the device was reasonable and medically necessary for you. Medicare will not pay for a device it does not deem reasonable and medically necessary.

A.R. 15794, 20669. Consequently, the Secretary determined that Bionicare, and not the beneficiaries, would be held liable for the costs of the non-covered claims. A.R. 15794, 20669.

Plaintiff's motion for summary judgment challenges the Secretary's rejection of the subject ABNs as improper. However, this Court instead finds these decisions to be reasonable and supported by evidence in the record. "Generic ABNs" are defined as "routine ABNs to beneficiaries which do no more than state that Medicare denial of payment is possible." MCPM Ch. 30, § 40.3.6.1. On the other hand, an ABN may successfully protect the supplier from liability if it "specif[ies] the service and a genuine reason that denial by Medicare is expected." *Id.* In light of these guidelines, the ABNs at issue were properly considered to be generic because they merely suggest that a payment denial is possible and do not clearly state that it is expected. In addition, the ABNs state only that "Medicare will not pay for a device it does not

deem reasonable and medically necessary." A.R. 15794, 20669. This is generic statement that does not provide sufficient details concerning the "genuine reason that denial by Medicare is expected." MCPM Ch. 30, § 40.3.6.1.

Plaintiff's opposition brief further contends that the Secretary alone should assume liability for the uncovered claims under 42 U.S.C. § 1395pp(a), because Bionicare, as well as the beneficiaries, could not be charged with advance notice of a coverage denial. As an initial matter, reviewing courts normally consider an argument that was not included in an opening brief to be waived. *See Carter v. R.C. Lee*, 283 F.3d 240, 252 n.11 (4th Cir. 2002). Nonetheless, Plaintiff's untimely argument also fails on the merits. The Medicare regulations provide that a supplier "is considered to have known that the services were not covered" if a Medicare contractor informed the supplier that "the services furnished were not covered, or that similar or reasonably comparable services were not covered." 42 C.F.R. § 411.406; *see also* HCFA Ruling 95-1 (Dec. 1995) at 19, 28 (Def.'s Ex. F) (finding that receipt of notice of non-coverage constitutes sufficient notice "for all subsequent claims involving that same service or item under similar or reasonably comparable conditions"). In this case it is undisputed that the Medicare contractors have denied several of Bionicare's early claims for the BIO-1000. Furthermore, the regulations provide that a supplier is "considered to have known that the services were not covered" in situations where it "informed the beneficiary" that "services were not covered." 42 C.F.R. § 411.406(d)(1); *see also* HCFA Ruling 95-1 at 28-29 (noting that where a provider issues "written notice of the likelihood of Medicare payment denial for a service or item to the beneficiary," this constitutes "sufficient evidence that the provider knew or should have known that the services or items would be denied"). It is undisputed in this case that Bionicare submitted ABNs to its beneficiaries. Therefore, this Court easily reaches the conclusion that

Bionicare knew that its subsequent claims would likely be denied coverage. Accordingly, Plaintiff cannot receive shelter from liability under 42 U.S.C. § 1395pp.

CONCLUSION

For the reasons stated above, this Court concludes that Plaintiff's Motion for Summary Judgment (Paper No. 39) is DENIED and Defendant's Motion for Summary Judgment (Paper No. 44) is GRANTED. A separate Order follows.

Dated: September 3, 2010

/s/
Richard D. Bennett
United States District Judge